K073006 Page 1 of 2

510(k) Summary

MAY 29 2008

OSTEOTRANS™-MX
Bioabsorbable Bone Fixation System

Submitter's name :	Takiron Co., Ltd.
Submitter's address:	3-13 Azuchi-machi 2-chome, Chuo-ku, Osaka 541-0052, Japan
Contact Person :	Kunihiro Hata Regulatory Affairs Specialist 7-1-19, Minatojimaminamimachi, Chuo-ku, Kobe, Hyogo, 650-0047, Japan Phone: +81 78 306 2601 Fax: +81 78 306 2606
Date prepared:	October 23, 2007
Trade or proprietary name:	OSTEOTRANS™-MX Bioabsorbable Bone Fixation System
Common or usual name:	Bioabsorbable bone fixation plate and screw
Classification name:	Cranioplasty plate and screw, Bone plate and screw, Class II
Device product code:	HRS - 21 CFR 888.3030 Plate, Fixation, Bone HWC - 21 CFR 888.3040 Screw, Fixation, Bone GWO - 21 CFR 882.5320 Plate, Cranioplasty, Preformed, Alterable HBW - 21 CFR 882.5360 Fastener, Plate, Cranioplasty

Establishment Registration Number:
Takiron Co., Ltd. has not yet obtained an Establishment Registration Number.

Legally Marketed Predicate Devices:

1. Inion Ltd.; Inion CPS™ 1.5/2.0/2.5 Bioabsorbable Fixation System (K010352)
2. Biomet, Inc.; LactoSorb® Trauma Plating System (K992355, K971870)
3. Codman & Shurtleff, Inc.; Codman® Craniosorb™ Absorbable Fixation System (K992905, K003549)
4. Bioplate Inc.; Modified plate design for use in conjunction with the Bioplate Rigid Bone Plating System for Craniomaxillofacial Surgery (K062819)
5. Takiron Co., Ltd.; OSTEOTRANS™-MX Bioabsorbable Bone Fixation System (K061881)

Intended Use:
The OSTEOTRANS™-MX Bioabsorbable Bone Fixation System is intended for use in trauma and reconstructive procedures of the craniofacial skeleton, including fracture of the cranium, infant craniofacial surgery (i.e. craniosynostosis, congenital malformations), pediatric reconstructive procedures, reconstructive procedures of the cranium, craniotomy flap fixation.

Device Description:
The OSTEOTRANS™-MX Bioabsorbable Bone Fixation System devices are the sterile, single-use bone plates, meshes and screws manufactured from composites of hydroxyapatite and poly-L-lactide (HA/PLLA). Plates, meshes and screws are provided with various shapes and sizes typical of other marketed fixation devices.

Used properly, in the presence of adequate immobilization, the OSTEOTRANS™-MX Bioabsorbable Bone Fixation System devices maintain accurate alignment of bone fractures and osteotomies.

Summary of Technology:
The OSTEOTRANS™-MX Bioabsorbable Bone Fixation System has the same technological characteristics (i.e., design and material) when compared to the predicate devices.
Performance data demonstrate that the OSTEOTRANS™-MX Bioabsorbable Bone Fixation System has the requisite strength and favorable degradation profile to provide sufficient and sustained bone fixation for intended uses.

Substantial equivalence
The OSTEOTRANS™-MX Bioabsorbable Bone Fixation System is indicated for the same uses and anatomical regions as the predicate devices.
The OSTEOTRANS™-MX Bioabsorbable Bone Fixation System is identical with the implants in the previously 510(k) cleared OSTEOTRANS-MX Bioabsorbable Bone Fixation System (K061881) in terms of composition, manufacturing method, sterilization method and packaging solution.
The OSTEOTRANS™-MX Bioabsorbable Bone Fixation System has very similar physical design features and functional characteristics as the other predicate devices.
Therefore the OSTEOTRANS™-MX Bioabsorbable Bone Fixation System is substantially equivalent in design, materials and intended use and principles of operation to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 29 2008

Takiron Co., Ltd.
% Mr. Kunihiro Hata
Regulatory Affairs Specialist
7-1-19, Minatojimaminamimachi,
Chuo-ku, Kobe, Hyogo, 650-0047
Japan

Re: K073006
Trade/Device Name: OSTEOTRANS™-MX Bioabsorbable Bone Fixation System
Regulation Number: 21 CFR 882.5320
Regulation Name: Preformed alterable cranioplasty plate.
Regulatory Class: Class II
Product Code: GWO, HBW
Dated: April 7, 2008
Received: April 7, 2008

Dear Mr. Hata:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

Applicant: Takiron Co., Ltd.
510(k) Number (if known): K073006
Device Name: OSTEOTRANS™-MX Bioabsorbable Bone Fixation System

Indications For Use:

The OSTEOTRANS™-MX Bioabsorbable Bone Fixation System is intended for use in trauma and reconstructive procedures of the craniofacial skeleton, including fracture of the cranium, infant craniofacial surgery (i.e. craniosynostosis, congenital malformations), pediatric reconstructive procedures, reconstructive procedures of the cranium, craniotomy flap fixation.

Prescription Use X OR Over-The-Counter Use No
(Per 21 CFR 801.109)

(Please do not write below this line—continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark A. Cohen for mxn

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K073006